CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 201023

CHEMISTRY REVIEW(S)



Application:

NDA 201023/000

Action Goal:

Stamp Date:

31-MAR-2010

District Goal:

24-MAY-2010

R itory:

30-SEP-2010

Applicant:

SANOFI AVENTIS SPA

Brand Name:

CABAZITAXEL (XRP6258)

.

55 CORORATE DR

Estab. Name:

9:

BRIDGEWATER, NJ 08807

Generic Name:

Priority:
Org. Code:

1 150

Product Number; Dosage Form; Ingredient; Strengths

001; SOLUTION, CONCENTRATE; CABAZITAXEL; 60MG/1.5ML

Application Comment:

PRIORITY PROSTATE CANCER NDA WITH SHORTENED REVIEW CLOCK- 8 WEEK REVIEW CLOCK. REQUEST

COMPLIANCE OVERALL RECOMMENDATION BY 5/24/10 (on 08-APR-2010 by D. MESMER (HFD-800) 301-796-4023)

FDA Contacts:

D. MESMER

Project Manager

(HFD-800)

301-796-4023

X. CHEN
H. SARKER

Review Chemist Team Leader

(HFD-150)

301-796-1337 301-796-1747

Overall Recommendation:

ACCEPTABLE

on 03-MAY-2010

by M. STOCK

(HFD-320)

301-796-4753

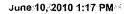
June 10, 2010 1:17 PM

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Establishment: CFN: **FEI:** (b) (4) (b) (4) DMF No: AADA: Responsibilities: Estab. Comment: Profile: OAI Status: NONE Milestone Name Milestone Date Request Type Planned Completion Decision Creator Comment Reason SUBMITTED TO OC 08-APR-2010 MESMERD OC RECOMMENDATION 21-APR-2010 ACCEPTABLE **STOCKM** BASED ON FILE REVIEW



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Establishment:

CFN: 9610119

FEI: 3002808000

AVENTIS PHARMA LTD.

9 QUAL JULES GUESDE

VITRY-SUR-SEINE, , FRANCE

DMF No:

(b) (4)

AADA:

Responsibilities:

DRUG SUBSTANCE LABELER

DRUG SUBSTANCE MANUFACTURER

DRUG SUBSTANCE PACKAGER

DRUG SUBSTANCE RELEASE TESTER DRUG SUBSTANCE STERILITY TESTER

Estab. Comment:

EMAIL FROM ELIZABETH PHILPY ON 4/7/10 INSTRUCTS THAT INFORMATION SUBMITTED FOR BOTH SANOFI-AVENTIS RECHERCHE & DÉVELOPPEMENT AT 13 QUAI JULES GUESDE AND SANOFI CHIMIE AT 9 QUAI JULES GUESDE SHOULD BE SUBMITTED UNDER THIS FEI NUMBER, 3002808000. SPONSOR INDICATES AT #13 QUAI JULES GUESDE: MANUFACTURING OF THE DRUG SUBSTANCE FROM (b) (4) AND (b) (4) AND MICROBIAL CONTAMINATION TESTING

OF THE DRUG SUBSTANCE

AT 9 QUAI JULES GUESDE: TESTING AND RELEASE OF (b) (4)

TESTING AND RELEASE, PACKAGING AND LABELING OF THE DRUG SUBSTANCE.

CONTACT NAME FOR #13 IS :MARIE-PIERRE IMBERT

QUALITY ASSURANCE MANAGER

MARIE-PIERRE.IMBERT@SANOFI-AVENTIS.COM

TEL: 33.1.58.93.88.66

FAX: 33.1.58.93.30.61 (on 07-APR-2010 by D. MESMER (HFD-800) 301-796-4023)

PLEASE REFER TO FACTS ASSIGNMENT IDS 1157497 AND 1157501, WHICH WERE ISSUED FOR THIS PRODUCT PRIOR TO SUBMISSION DUE TO THE EXPEDITED STATUS OF THE APPLICATION. (on 09-APR-2010 by M. STOCK (HFD-320)

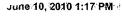
301-796-4753)

Profile:

NON-STERILE BULK BY CHEMICAL SYNTHESIS

OAI Status: NONE

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
SI' TITTED TO OC	08-APR-2010				MESMERD
SUBMITTED TO DO	09-APR-2010	Product Specific			STOCKM
ASSIGNED INSPECTION TO IB	16-APR-2010	Product Specific			JOHNSONE
DO RECOMMENDATION	03-MAY-2010			ACCEPTABLE	STOCKM
EXPEDITED COMPLIANCE REVIEW DONE BY DOUG CAMPBELL.				INSPECTION	
OC RECOMMENDATION	03-MAY-2010			ACCEPTABLE	STOCKM
				DISTRICT RECOMMENDATION	



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Establishment:

CFN: 9610433

FEI: 1000541557

AVENTIS PHARMA LTD.

RAINHAM ROAD SOUTH

DAGENHAM, , UNITED KINGDOM

AADA:

Responsibilities:

FINISHED DOSAGE MANUFACTURER

Estab. Comment:

MANUFACTURING, TESTING AND RELEASE, PACKAGING AND LABELING OF THE DRUG PRODUCTS (CABAZITAXEL CONCENTRATE FOR SOLUTION FOR INFUSION AND SOLVENT FOR DILUTION) (on 07-APR-2010 by D. MESMER (HFD-

800) 301-796-4023)

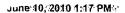
Profile:

DMF No:

STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS

OAI Status: NONE

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator	
Comment				Reason		
SUBMITTED TO OC	08-APR-2010				MESMERD	
SUBMITTED TO DO	08-APR-2010	10-Day Letter			STOCKM	
DO RECOMMENDATION	16-APR-2010			ACCEPTABLE	JOHNSONE	
				BASED ON FILE REVIEW		
OC RECOMMENDATION	18-APR-2010			ACCEPTABLE	INYARDA	
		•		BASED ON PROFILE		
				DISTRICT RECOMMENDATION		



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